

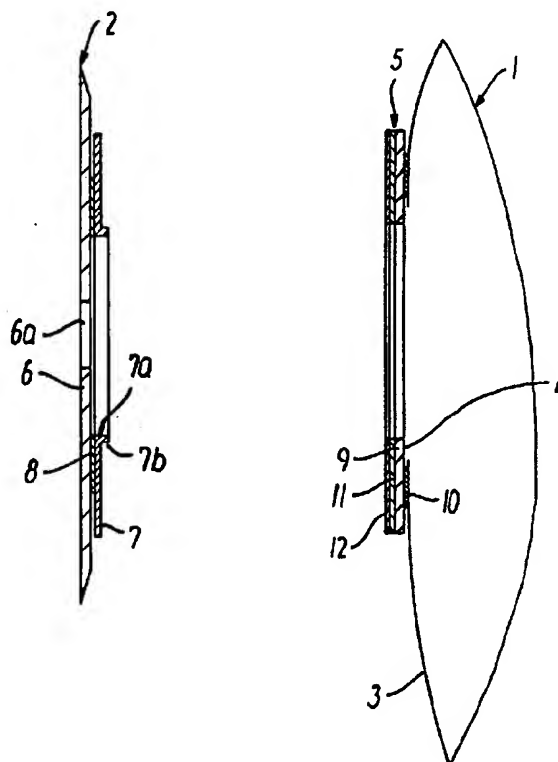


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(21) International Application Number: PCT/DK96/00223 (22) International Filing Date: 24 May 1996 (24.05.96) (30) Priority Data: 0607/95 29 May 1995 (29.05.95) DK (71) Applicant: COLOPLAST A/S [DK/DK]; 2-8 Bronzevej, DK-3060 Espergårde (DK). (72) Inventor: OLSEN, Hans; 85B Usseørd Kongevej, DK-2970 Hørsholm (DK). (74) Agents: RAFFNØSE, Knud, Rosenstand et al.; International Patent-Bureau, Høje Taastrup Boulevard 23, DK-2630 Taasttrup (DK).		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: AN OSTOMY COLLECTING SYSTEM**(57) Abstract**

The ostomy collecting system comprises a collecting bag (1) having an inlet opening (4) formed in a bag wall and with surrounding connecting elements (5) for connection with a stoma in a user, and a carrier device (2) for the collecting bag. The carrier device comprises a base plate (6) for fastening on the user and a substantially annular first flange (7) connected to the base plate via a first connecting section (8). The connecting elements comprise a substantially annular second flange (9), which is fixedly connected to the collecting bag via a substantially annular second connecting section (10) and is designed for removable and adhesive connection with said first flange. The first and the second flanges (7, 9) are connected with the base plate (6) and the collecting bag (1), respectively, in such a manner that the outer radius of said second connecting section (10) exceeds the outer radius of said first connecting section (8) by a value which at least equals the total thickness of the first and the second flanges (7, 9). The adhesive connection between the collecting bag and the carrier device is provided by a layer (11) of adhesive applied on said second flange (9) and capable of repeated adhesion with the first flange, and the first and the second flanges are made from a flexible and resilient material. Both the first and the second flanges (7, 9) are formed as discs of cellular plastic material.



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An ostomy collecting system

The present invention relates to an ostomy collecting system comprising a collecting bag having an inlet opening formed in a bag wall and with surrounding
5 connecting elements for connection with a stoma in a user, and a carrier device for the collecting bag, the carrier device comprising a base plate for fastening on the user and a substantially annular first flange, which is fixedly connected to the base plate via a substan-
10 tially annular first connecting section, the connecting elements comprising a substantially annular second flange, which is fixedly connected to the collecting bag via a substantially annular second connecting section and is adapted for removable and adhesive connection
15 with said first flange.

A collecting system of this type is known from EP patent application No. 0 276 043, a flange for adhesive connection with the flange of the collecting bag or with the bag itself being fastened on a base plate in the
20 form of an adhesive pad.

In such a collecting system, the base plate of the carrier device must be able to remain on the user over a long period of time, for example up to 8-10 days. During this whole period of time, the carrier device
25 must be capable of undergoing deformation owing to the user's movements, washing, exposure to bag replacements, etc. Conventionally, the base plate of such a carrier device is designed as a thin adhesive foil, optionally with some sort of stiffening reinforcement disc for
30 maintaining a plane adhesive surface for the bag. However, such a reinforcement disc prevents the base plate from following the contours of the body when the user moves, and it does not provide the desired shock absorbing effect between the collecting bag and the

user, which, of course, reduces comfort. A less rigid disc would be able to follow the base plate during such movements, to be sure, but would thus exert a pull in it, which, in addition to transmitting an unpleasant
5 pulling effect to the user's skin, also weakens the adhesive effect between base plate and skin. Furthermore, the adhesive surface facing the bag will not in that case remain plane owing to the inevitable deformations, which results in problems of rearranging the bag
10 on the user.

In the above EP patent application, an attempt has been made to eliminate these problems by connecting a rigid flange with the base plate via a flexible sheet, which, however, provides an unstable and insecure
15 connection. Furthermore, the adhesive connection taught between bag and carrier device is provided either by a number of layers of adhesive applied to the flange of the base plate and activated one after the other, which reduces the number of times to which the base plate may
20 be exposed to a change of bag to the number of layers of adhesive, or by using a new bag with a fresh layer of adhesive, which renders the system more expensive in use.

Against this background, the object of the present
25 invention is to provide a collecting system of the type mentioned in the introduction, in which the connecting surface between the collecting bag and the carrier device is maintained largely independently of the deformation of the base plate caused by, for example,
30 the user's movements, but which is nevertheless stable and continues to exhibit an even and flexible adhesive surface without creases and ditches between the flanges of the bag and the base plate. It is a further object that it must be possible to remove and reinstall one or

more bags repeatedly without any reduction in the life of the base plate.

This is achieved according to the invention with a collecting system which is characterized in that the
5 first and the second flanges are connected with the base plate and the collecting bag, respectively, in such a manner that the outer radius of said second connecting section exceeds the outer radius of said first connecting section by a value which at least equals the total
10 thickness of the first and the second flanges, that the adhesive connection between the collecting bag and the carrier device is provided by a layer of adhesive applied on said second flange and capable of repeated adhesion with said first flange, and that the first and
15 the second flanges are made from a flexible and resilient material.

This design of the collecting system according to the invention achieves a connection between carrier device and collecting bag, which is stable against
20 displacement forces, and which acts as a shock absorbing element. The difference in radius between the two connecting sections between the first flange and the base plate, and the second flange and the collecting bag, respectively, has the result that the force which
25 would normally be transmitted to the user's skin during use of the collecting system will instead be absorbed by the flanges, which in this design are capable of deformation both in the plane of the flanges and at a right angle thereto, as the point of action of the force
30 will be located in a cantilever area, which provides a good resilient effect. The flange connected with the base plate exhibits a good adhesive surface, as the resilience of both the first and the second flanges causes them to return to their original plane state
35 after deformation. Finally, the reusable layer of

adhesive on the flange connected with the collecting bag means that the bag can be removed from the carrier device repeatedly, and that, for example, in case of venting, when the bag is merely lifted, it is not
5 necessary to activate a new layer of adhesive or use a new bag.

The first and the second flanges are preferably formed as discs of a cellular plastic material, which provides a good shock absorbing and resilient action and
10 also has the effect that the weight of the collecting system can be kept down.

Other embodiments of the invention are provided in claims 3-5.

The invention will now be described in further
15 detail below with reference to the schematic drawing, in which

Figs. 1 and 2 show perspective views of a carrier device and a collecting bag, respectively, of a collecting system according to the invention,

20 Fig. 3 shows a section along the line III-III in Fig. 1, and

Fig. 4 shows a section along the line IV-IV in Fig. 2.

The ostomy collecting system shown in Figs. 1 and
25 2 comprises a collecting bag 1 for collection of faeces and a carrier device 2 for fastening the bag 1 around an intestinal orifice in the form of a so-called stoma in the user's abdominal wall, and for this purpose has an inlet opening 4 in a bag wall 3. The bag 1 may either
30 be closed at the bottom as shown (Fig. 4) or be formed with a drainage device for emptying of its contents. The inlet opening 4 is surrounded by connecting elements generally designated 5 for connecting the bag 1 with the carrier device 2. The carrier device comprises a base
35 plate 6 which is designed to be adhered to the user's

skin by means of a skin-friendly adhesive applied on the back of the base plate. The base plate 6 carries a first flange or base plate flange 7, in which is formed a hole 7a with an upright collar 7b, the function of which will be explained below.

The structure of the carrier device 2 and the collecting bag 1 with associated connecting elements 5 is shown in further detail in Figs. 3 and 4, respectively.

10 As it appears, the base plate flange 7 is fastened to the base plate 6 with a layer 8 of adhesive applied in a substantially annular connecting section having an internal diameter corresponding to that of the hole 7a in the base plate flange 7 and having an external
15 diameter so that a rim portion of the flange 7 protrudes beyond the layer 8 of adhesive. The base plate flange 7 may, for example, be moulded in a water-repellent cellular plastic material, such as ethylene vinyl acetate (EVA) or polyurethane (PUR), with closed cells
20 so that the cellular plastic material does not absorb liquid.

The fastening elements 5 on the bag 1 are constructed from a second flange or bag flange 9 which, in the embodiment shown, is fastened to the bag wall 3 by
25 means of a substantially annular connecting section in the form of a layer 10 of adhesive in such a manner that a rim portion of the bag flange 9 protrudes beyond the layer 10 of adhesive. The outer radius of the layer 10 of adhesive exceeds the outer radius of the layer 8 of
30 adhesive between the base plate flange 7 and the base plate 6 by a value at least equalling the total thickness of the base plate flange 7 and the bag flange 9. Of course, the bag flange 9 may also be fastened to the bag 3 through other means, for example by welding, and
35 like the base plate flange 7 it consists of a moulded

cellular plastic material, such as EVA cellular plastic or PUR cellular plastic. On the side facing away from the bag, over substantially all its surface the flange 9 is coated with a thin, washable layer 11 of adhesive, 5 which may, for example, be a hydrogel adhesive, an acrylate adhesive or an adhesive of the hot-melt type. The layer 11 of adhesive is applied in a thin layer, partly to keep down thickness, partly to maintain the flexibility and resilience of the bag flange. This 10 application may be effected, for example, by coating, spraying or application in a suitable pattern. In the delivery state of the bag, the layer 11 of adhesive is covered by an adhesive-repellent cover layer 12.

When the collecting system according to the 15 invention is used, the carrier device 2 is arranged on the user, the base plate 6 being placed against the user's skin, and the stoma being passed out through the hole 6a. The cover layer 12 of the collecting bag is removed to uncover the layer 11 of adhesive, which is 20 subsequently adhered to the base plate flange 7 of the carrier device with simultaneous insertion of the stoma into the collecting bag through the inlet opening 4. At this stage, the upright collar 7b acts as a guide surface and thus prevents incorrect mounting of the 25 collecting bag, and in the assembled state of the collecting system it forms a passage for the stoma and thus protects the layer 11 of adhesive from faeces flowing out from the intestine.

C L A I M S

1. An ostomy collecting system comprising a collecting bag (1) having an inlet opening (4) formed in a bag wall and with surrounding connecting elements (5) for connection with a stoma in a user, and a carrier device (2) for the collecting bag, the carrier device comprising a base plate (6) for fastening on the user and a substantially annular first flange (7), which is fixedly connected to the base plate via a substantially annular first connecting section (8), the connecting elements comprising a substantially annular second flange (9), which is fixedly connected to the collecting bag via a substantially annular second connecting section (10) and is adapted for removable and adhesive connection with said first flange, characterized in that the first and the second flanges (7, 9) are connected with the base plate (6) and the collecting bag (1), respectively, in such a manner that the outer radius of said second connecting section (10) exceeds the outer radius of said first connecting section (8) by a value which at least equals the total thickness of the first and the second flanges (7, 9), that the adhesive connection between the collecting bag and the carrier device is provided by a layer (11) of adhesive applied on said second flange (9) and capable of repeated adhesion with said first flange, and that the first and the second flanges are made from a flexible and resilient material.

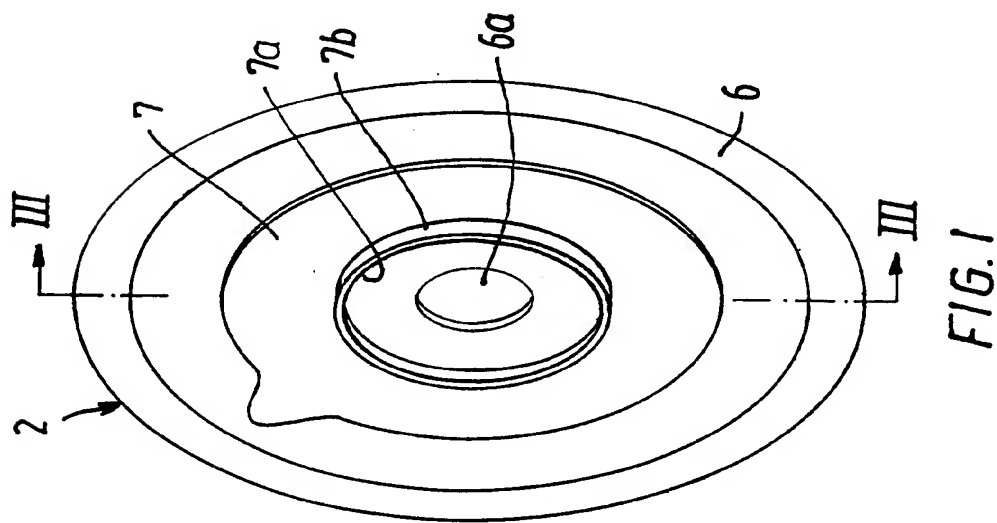
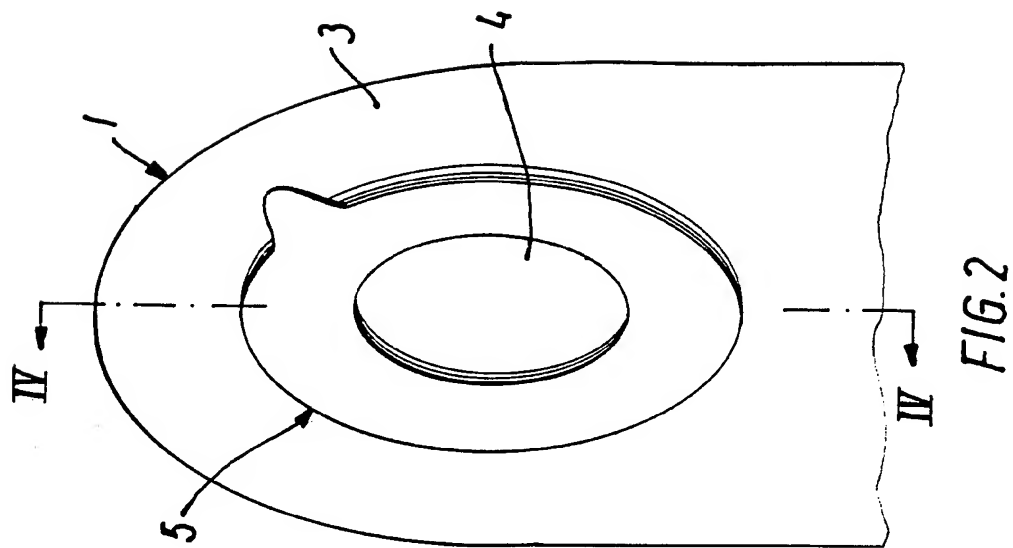
2. A collecting system according to claim 1, characterized in that the layer (11) of adhesive is washable.

3. A collecting system according to claim 1 or 2, characterized in that both the first and the second flanges (7, 9) are formed as discs of a cellular plastic material.

4. A collecting system according to claim 3, characterized in that said cellular plastic material is a polyurethane cellular plastic or an ethylene vinyl acetate cellular plastic.

- 5 5. A collecting system according to any one of the preceding claims, characterized in that the layer (11) of adhesive is applied to the second flange (9) in a layer thickness substantially smaller than the thickness of said second flange.

1/2



2/2

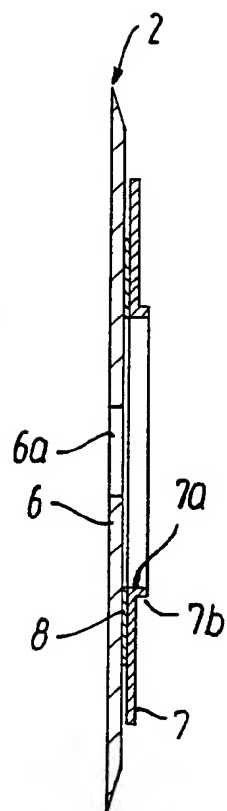


FIG. 3

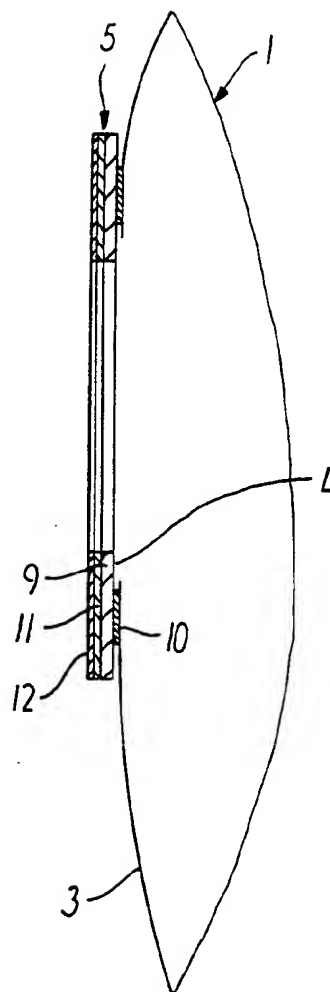


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 96/00223

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/448

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

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QUESTEL 2

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4808173 A (PAUL O. KAY), 28 February 1989 (28.02.89), column 3, line 18 - column 4, line 36, figure 2 --	1-5
X	US 5346482 A (MICHAEL METZ ET AL.), 13 Sept 1994 (13.09.94), column 3, line 14 - column 4, line 30, figures 2-3 --	1-5
A	GB 2151482 A (CRAIG MEDICAL PRODUCTS LIMITED (UNITED KINGDOM)), 24 July 1985 (24.07.85), figure 1 --	1-5



Further documents are listed in the continuation of Box C.



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Date of the actual completion of the international search

3 October 1996

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2153232 A (CRAIG MEDICAL PRODUCTS LIMITED (UNITED KINGDOM)), 21 August 1985 (21.08.85), figure 12 -----	1-5

INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4808173	28/02/89	AU-B- 592885	25/01/90
		AU-A- 7634887	11/02/88
		BE-A- 1001426	31/10/89
		CA-A- 1282293	02/04/91
		DE-A, C- 3726198	11/02/88
		FR-A- 2602418	12/02/88
		GB-A, B- 2193439	10/02/88
		IE-B- 60074	01/06/94
		JP-C- 1761823	28/05/93
		JP-B- 4044548	22/07/92
		JP-A- 63043676	24/02/88
		NL-A- 8701821	01/03/88
		SE-C- 500573	18/07/94
		SE-A- 8703009	08/02/88

US-A- 5346482	13/09/94	AU-B- 662708	07/09/95
		AU-A- 5794794	06/10/94
		CA-A- 2119613	03/10/94
		EP-A- 0623327	09/11/94
		FI-A- 941297	03/10/94
		JP-A- 6304197	01/11/94
		NO-A- 940992	03/10/94
		NZ-A- 260189	28/05/96

GB-A- 2151482	24/07/85	AU-B- 581419	23/02/89
		AU-A- 3650384	27/06/85
		CA-A- 1264134	02/01/90
		DE-A- 3485482	05/03/92
		DE-A- 3485548	09/04/92
		DE-A- 3485549	09/04/92
		DK-B- 168688	24/05/94
		EP-A, B- 0146367	26/06/85
		SE-T3- 0146367	
		EP-A, B- 0276042	27/07/88
		SE-T3- 0276042	
		EP-A, B- 0276043	27/07/88
		SE-T3- 0276043	
		EP-A, B- 0276898	03/08/88
		SE-T3- 0276898	
		GB-A, B- 2153232	21/08/85
		JP-C- 1819047	27/01/94
		JP-B- 5024781	08/04/93
		JP-A- 6070950	15/03/94
		JP-A- 60156457	16/08/85
		US-A- 4701169	20/10/87

INTERNATIONAL SEARCH REPORT

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GB-A- 2153232	21/08/85	AU-B- 581419	23/02/89
		AU-A- 3650384	27/06/85
		CA-A- 1264134	02/01/90
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		DE-A- 3485548	09/04/92
		DE-A- 3485549	09/04/92
		DK-B- 168688	24/05/94
		EP-A,B- 0146367	26/06/85
		SE-T3- 0146367	
		EP-A,B- 0276042	27/07/88
		SE-T3- 0276042	
		EP-A,B- 0276043	27/07/88
		SE-T3- 0276043	
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		SE-T3- 0276898	
		GB-A,B- 2151482	24/07/85
		JP-C- 1819047	27/01/94
		JP-B- 5024781	08/04/93
		JP-A- 6070950	15/03/94
		JP-A- 60156457	16/08/85
		US-A- 4701169	20/10/87
		GB-A,B- 2157567	30/10/85
		GB-A,B- 2162626	05/02/86
